AMENDMENTS

In the Claims

Please cancel all pending claims 1-32 and add new claims 33-41 as listed below:

1-32. (canceled)

33. (New) A pharmaceutical composition comprising recombinant N-acetylgalactosamine-4-sulfatase, a pharmaceutically acceptable carrier, and a polyoxyethylenesorbitan.

34. (New) A pharmaceutical composition comprising recombinant N-acetylgalactosamine-4-sulfatase, a pharmaceutically acceptable carrier, and polyoxyethylenesorbitan 20 or 80.

35. (New) A pharmaceutical composition comprising recombinant N-acetylgalactosamine-4-sulfatase, a pharmaceutically acceptable carrier, and polyoxyethylenesorbitan 20.

36. (New) A pharmaceutical composition comprising recombinant N-acetylgalactosamine-4-sulfatase, a pharmaceutically acceptable carrier, and polyoxyethylenesorbitan 80.

37. (New) The pharmaceutical composition of any one of claims 33 through 36, wherein said polyoxyethylenesorbitan concentration is about 0.001% (W/V).

38. (New) The pharmaceutical composition of any one of claims 33 through 36 wherein said recombinant N-acetylgalactosamine-4-sulfatase is a human N-acetylgalactosamine-4-sulfatase.

39. (New) The pharmaceutical composition of claim 37 wherein said recombinant N-acetylgalactosamine-4-sulfatase is a human N-acetylgalactosamine-4-sulfatase.

40. (New) A pharmaceutical composition suitable for administration to humans comprising recombinant human N-acetylgalactosamine-4-sulfatase and a pharmaceutically acceptable carrier, said composition having the following characteristics:

(a) activity by fluorescence assay is between about 20,000 and 120,000 mUnits;
(b) absence of detectable adventitious viruses;
(c) absence of detectable mycoplasma;
(d) endotoxin level by LAL assay of about 2 EU/mL or less;
(e) about 600 or less particulates of 25 um in size per vial;
(f) about 6000 or less particulates of 10 um in size per vial;
(g) pH between about 5.5 and 6.8;
(h) protein concentration of about 0.8 to 1.2 mg/mL;
(i) one major band between about 65 and 70 kDa detectable on SDS-PAGE;
(j) greater than about 95% purity by RP-HPLC; and
(k) calculated specific activity of between about 40,000 and 80,000 mUnits per milligram of protein.

41. (New) The pharmaceutical composition of claim 40 produced by a purification process comprising the steps of:

(a) harvesting fluid obtained from a culture of cells transformed with a gene encoding a recombinant N-acetylgalactosamine-4-sulfatase;
(b) running the fluid on a DEAE sepharose column;
(c) running the fluid on a Blue sepharose FF column;
(d) running the fluid on a copper chelating sepharose column;
(e) running the fluid on a phenyl sepharose column; and
(f) diafiltering the purified recombinant human N-acetylgalactosamine-4-sulfatase.

In the Drawings

Please replace Figs. 1-2 with enclosed formal Figures 1-2. The content of these figures is identical to those originally filed.